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EXAMINER	
DEAK, LESLIE R	
ART UNIT	**PAPER NUMBER**
3761	

MAIL DATE	DELIVERY MODE
11/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,468	ALTMAN, SANFORD D.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-29 and 31-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-29 and 31-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 3-10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 3 and 6-10 depend from claim 2, which has been cancelled. For the purposes of examination, the Examiner is interpreting the claims to depend from independent claim 1.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 6, 7, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,099,58 to Sorenson et al.

In the specification and figures, Sorenson discloses the apparatus as claimed by applicant. With regard to claims 1 and 29, Sorenson discloses a dual-lumen catheter with an interior or arterial lumen 32 having an inner and outer surface and a distal end, and a proximal end mounted in a hollow hub 12. Sorenson further discloses an exterior or venous lumen 34 with an inner and outer surface, distal end, proximal end, with a single aperture at the distal end (see column 2, lines 40-65, FIG 2). The catheters 32,

34 are arranged in a coaxial configuration with the inner or arterial catheter 32 extending beyond the distal end of the outer or venous lumen 34 (see column 2, lines 66-68, FIG 2).

With regard to claims 6-7, as interpreted by the Examiner, Sorenson illustrates that the distal ends of the venous or outer and arterial or inner catheters are tapered (see FIGS 2-3).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 3-5, 11-16, 20-25, 27, 28, and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,099,58 to Sorenson et al in view of US 6,758,836 to Zawacki.

In the specification and figures, Sorenson discloses the apparatus substantially as claimed by applicant (see rejection above).

With regard to claims 3-5, as interpreted by the Examiner, Sorenson fails to disclose how far the inner or arterial lumen extends beyond the distal end of the outer, or venous lumen. Zawacki discloses a dual-lumen catheter wherein the inner lumen 30 of catheter 10 is slideable, or adjustable with respect to the distal end of the outer lumen 20 (see column 4, lines 1-18, FIGS 2, 3). Zawacki teaches that the ability to alter the

position of the distal end of the inner tube with respect to the outer tube is especially useful in order to relieve blockages in flow. Zawacki's disclosure suggests that the catheter 10 and its lumens 20, 30, are capable of being deployed at the distances claimed by applicant in order to provide for efficient fluid movement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to deploy the catheter disclosed by Zawacki with the distal ends of the lumens separated by the distance claimed by applicant, in order to provide flexibility in blockage alleviation, as taught by Zawacki.

With regard to claims 11 and 20, Sorenson fails to disclose the particular shapes of the catheters. Zawacki discloses that the catheter lumens may comprise a circle-C or double-D configuration that are interchangeable with the coaxial configuration (see column 4, lines 45-48). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to form the catheter disclosed by Sorenson in a circle-C or double-D configuration, since Zawacki discloses that such shapes are functional equivalents to the coaxial configuration.

With regard to claims 12-14 and 21-23, Sorenson fails to disclose how far the inner or arterial lumen extends beyond the distal end of the outer, or venous lumen. Zawacki discloses a dual-lumen catheter wherein the inner lumen 30 of catheter 10 is slideable, or adjustable with respect to the distal end of the outer lumen 20 (see column 4, lines 1-18, FIGS 2, 3). Zawacki teaches that the ability to alter the position of the distal end of the inner tube with respect to the outer tube is especially useful in order to relieve blockages in flow. Zawacki's disclosure suggests that the catheter 10 and its

lumens 20, 30, are capable of being deployed at the distances claimed by applicant in order to provide for efficient fluid movement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to deploy the catheter disclosed by Zawacki with the distal ends of the lumens separated by the distance claimed by applicant, in order to provide flexibility in blockage alleviation, as taught by Zawacki.

With regard to claims 15-16, Sorenson illustrates that the distal ends of the venous or outer and arterial or inner catheters are tapered (see FIGS 2-3).

With regard to claims 24 and 25, Sorenson fails to disclose that the distal end of the venous lumen comprises a plurality of shaped apertures. Zawacki illustrates that both the inner and outer lumens, 30, 20/24, comprise a plurality of circular apertures 36, 26 (see FIG 1). Accordingly, the references taken together suggest the plurality of distal apertures as illustrated by Zawacki in order to provide varied flow ports in case one gets blocked.

With regard to claim 27, Sorenson fails to disclose that the catheter is constructed of the claimed materials. Zawacki discloses that the catheter may be made of thermoplastics such as PTFE (see column 3, lines 24-33).It would have been obvious to one having ordinary skill in the art at the time the invention was made to use thermoplastics such as PTFE in the catheter disclosed by Sorenson, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07.

With regard to claim 28, Sorenson fails to disclose that the catheter comprises the claimed reinforcing materials. Zawacki discloses that reinforcing substances to reduce kinking may be used in the construction of the catheter, including wire (which is a metal formed as a flexible thread), which meets applicant's claim drawn to a metal (see column 4, lines 34-38). Therefore, it would have been obvious to add metal as disclosed by Zawacki to the catheter disclosed by Sorenson in order to reinforce the catheter structure, as taught by Zawacki.

With regard to claim 31, Sorenson discloses that the claimed catheter may be inserted into a patient, but does not specifically disclose the claimed method steps. Zawacki discloses providing the claimed catheter, inserting it into a venotomy site (see column 3, lines 7-22, column 9, lines 8-10), and using the catheter to remove blood, treat the removed blood, and return treated blood to the patient (see column 1, lines 15-20). With regard to applicant's recitation of the length of the lumens, Zawacki discloses that the inner lumen is slideable, meaning that the arterial lumen is capable of being disposed along the entire length of the venous lumen (see FIGS 2 and 3), meeting the limitations of the claim. Therefore, it would have been obvious at the time of invention to deploy the catheter disclosed by Sorenson in the manner disclosed by Zawacki, since the references, taken together, reasonably suggest the use of a coaxial dual-lumen catheter as disclosed by Sorenson in the method disclosed by Zawacki to remove, treat, and return blood to the patient.

With regard to claims 32 and 33, Sorenson and Zawacki suggest the method substantially as claimed by applicant with the exception of deploying the catheter in the

claimed location and threading the catheter over a guidewire. However, Zawacki specifically discloses that the catheter may be introduced so that the catheter lies at the junction of the superior vena cava and the right atrium and that the position of the inner and outer lumens may be adjusted to provide for the correct location of the lumens within the vasculature (see column 3, lines 7-67). Therefore, it would have been obvious to place the lumens of the catheter disclosed by Zawacki in the locations claimed by applicant, since Zawacki suggests such positioning and teaches that the catheter is adjustable. With regard to the guidewire, Zawacki discloses that the catheter may be provided with a guidewire, indicating that in some applications, the catheter is deployed over a guidewire into the correct position (see column 3, liens 7-22). Therefore, it would have been obvious to deploy the catheter disclosed by Zawacki over a guidewire as claimed by applicant, since Zawacki teaches that the catheter may be supplied with a guidewire for deployment.

With regard to claim 34 Sorenson discloses a hub, but does not specifically teach that the catheters are replaceable. Zawacki discloses that the catheter assembly 10 comprises a hollow hub 40 that connects to the assembly (see FIG 1, column 3, lines 48-67). Zawacki further discloses that the inner lumen—which may act as either the venous lumen or arterial lumen, depending on the operation of the catheter (see column 4, lines 5-18)—is removable and replaceable (see column 1, lines 61-67).

With regard to claim 35 Sorenson fails to disclose the exact location of the insertion point. Zawacki discloses that the cathether may be inserted into one of the

large central veins, which may include a jugular or subclavian vein (see column 2 line 65 to column 3, line 22).

6. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,099,58 to Sorenson et al in view of US 6,595,966 to Davey et al.

In the specification and figures, Sorenson suggests the device substantially as claimed by applicant (see rejection above) with the exception of a therapeutic agent.

With regard to claim 26, Davey discloses that a surface of the conduit may be treated with heparin, an anticoagulant, in order to prohibit deposit of materials on the surface of the conduit (see column 2, lines 25-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter suggested by the prior art with a therapeutic agent such as an anticoagulant as disclosed by Davey in order to prevent deposit of materials on the surface of the conduit, as taught by Davey.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over over US 4,099,58 to Sorenson et al in view of US 5,683,640 to Miller et al.

In the specification and figures, Sorenson discloses the device substantially as claimed by applicant (see rejection above) with the exception of fusing the inner and outer lumens together.

Zawacki teaches that the slideable lumens of the catheter 10 may be locked into position by a mechanism at the proximal end of the catheter, but does not teach such a

locking at the distal end (see column 6, lines 1-60). Miller teaches a dual-lumen coaxial catheter for dialysis that is formed in one single piece in order to provide a smooth surface that reduces clots and a unitary structure that reduces tip breakage (see column 2, lines 33-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to fuse the lumens in the apparatus disclosed by the prior art into a single piece, as disclosed by Miller, in order to provide a smooth surface with reduced tip breakage, as taught by Miller.

8. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,099,58 to Sorenson et al in view of US 5,762,631 to Klein.

In the specification and figures, Sorenson suggests the device substantially as claimed by applicant (see rejection above) with the exception of a ridge or spoke attached between the outer and inner lumens. Examiner considers the ridge and the spoke claimed by applicant to be substantially similar, since all the limitations of the claimed spoke are part of the claimed ridge (that is, a ridge may function as a spoke). Klein discloses a coaxial dual-lumen catheter with elongate protrusions 25, 31, that are attached on the inner surface of the outer catheter or the outer surface of the inner catheter, respectively (see FIGS 3A, 3B, column 8, lines 17-24). The ridges or spokes assist in the positioning of the catheters relative to one another after deployment (see column 1, lines 50-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter suggested by

the prior art with the ridges or spokes disclosed by Klein in order to position the catheters relative to one another, as taught by Klein.

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over over US 4,099,58 to Sorenson et al in view of US 6,758,836 to Zawacki, further in view of US 5,683,640 to Miller et al.

In the specification and figures, Sorenson and Zawacki disclose the device substantially as claimed by applicant (see rejection above) with the exception of fusing the inner and outer lumens together.

Zawacki teaches that the slideable lumens of the catheter 10 may be locked into position by a mechanism at the proximal end of the catheter, but does not teach such a locking at the distal end (see column 6, lines 1-60). Miller teaches a dual-lumen coaxial catheter for dialysis that is formed in one single piece in order to provide a smooth surface that reduces clots and a unitary structure that reduces tip breakage (see column 2, lines 33-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to fuse the lumens in the apparatus disclosed by the prior art into a single piece, as disclosed by Miller, in order to provide a smooth surface with reduced tip breakage, as taught by Miller.

10. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,099,58 to Sorenson et al in view of US 6,758,836 to Zawacki, further in view of US 5,762,631 to Klein.

In the specification and figures, Zawacki and Sorenson suggest the device substantially as claimed by applicant (see rejection above) with the exception of a ridge or spoke attached between the outer and inner lumens. Examiner considers the ridge and the spoke claimed by applicant to be substantially similar, since all the limitations of the claimed spoke are part of the claimed ridge (that is, a ridge may function as a spoke). Klein discloses a coaxial dual-lumen catheter with elongate protrusions 25, 31, that are attached on the inner surface of the outer catheter or the outer surface of the inner catheter, respectively (see FIGS 3A, 3B, column 8, lines 17-24). The ridges or spokes assist in the positioning of the catheters relative to one another after deployment (see column 1, lines 50-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter suggested by the prior art with the ridges or spokes disclosed by Klein in order to position the catheters relative to one another, as taught by Klein.

Response to Arguments

11. Applicant's amendment and arguments, filed 25 September 2007, with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

12. Applicant argues that the Zawacki device does not disclose or suggest a coaxial dual lumen catheter that comprises a coaxial configuration through the catheter's entire length wherein the inner catheter extends from a single aperture in the outer lumen.

Examiner submits that the newly applied Sorenson reference meets the limitations of the amended claims.

13. Applicant further argues that the peaks and flat ridges disclosed by Klein fail to correspond to the instantly claimed ridges and spokes. Examiner respectfully disagrees. Klein discloses that the ridges or spokes assist in the positioning of the catheters relative to one another after deployment (see column 1, lines 50-55). It is the position of the Examiner that the peaks and ridges disclosed by Klein are functionally equivalent to the claimed ridge or spoke which positions the lumens relative to one another. Accordingly, the references, taken together, suggest a dual-lumen coaxial catheter with interior devices to position the catheters relative to one another, rendering the instantly claimed invention unpatentable over the prior art.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 4,385,631 Uthman

i. Catheter with coaxial configuration and tapered ends

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
13 November 2007